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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/520,567	08/24/2005	Pascal Furet	32572A US-PCT	5275
75074 7590 12/05/2008 NOVARTIS INSTITUTES FOR BIOMEDICAL RESEARCH, INC. 400 TECHNOLOGY SQUARE CAMBRIDGE, MA 02139				
EXAMINER RAO, DEEPAK R				
ART UNIT		PAPER NUMBER		
1624				
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12/05/2008		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/520,567

Applicant(s)

FURET ET AL.

Examiner

Deepak Rao

Art Unit

1624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 August 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11, 13 and 14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11, 13 and 14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-946)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/92)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

This office action is in response to the amendment filed on August 18, 2008.

Claims 1-11 and 13-14* are pending in this application.

**Note:* The status identifier for claims 10 and 13 indicates that these claims are “Withdrawn”. This is inaccurate. Claims 10 and 13 were not ‘withdrawn’ from consideration previously and the claims were fully examined and rejected as indicated in the office action mailed on September 21, 2007.

Withdrawn Rejections/Objections:

Applicant is notified that any outstanding rejection/objection that is not expressly maintained in this office action has been withdrawn or rendered moot in view of applicant’s amendments and/or remarks.

The following rejections are maintained:

1. Claim 13 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for the treatment of non-small cell lung carcinoma, does not reasonably provide enablement for a method for the treatment of a disease which responds to an inhibition of protein tyrosine kinase generally. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. The reasons from the previous office action (see pages 4-9) are incorporated here by reference.

Applicant indicates that 'claim 13 has been withdrawn'. This, however, is not correct. The claim was fully treated on its merits and rejected. Applicant did not respond to the rejection.

2. Claim 10 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 10 provides for the use of the compound of claim 1, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

3. Claim 10 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Applicant indicates that 'claim 10 has been withdrawn, and the rejection is moot'. This, however, is not correct. The claim was fully treated on its merits and was rejected in the previous office action. The rejection is not rendered moot, unless the claim is canceled. The above rejections are maintained for the reasons provided above.

Note: Applicant is advised that should claim 1 be found allowable, claim 10 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other

as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). Claim 10 recites the intended use for the compounds of claim 1 and does not contain any structural distinction from claim 1.

4. Claims 1-7, 10-11 and 14 are rejected under 35 U.S.C. 102(e) as being anticipated by Mueller et al., WO 03/049542 (filing date December 5, 2002). The instant claims read on reference disclosed compounds, see the structural formula (I) in page 1 and the corresponding compounds of Examples 3a and the compounds that correspond to formula 1.01 in Table 01.

Note: Applicant can not rely on foreign priority based on United Kingdom 0215844.2 (filed July 8, 2002) to overcome the rejection under 35 U.S.C. 102(e) because the priority document does not fully support the instant claims. The structural formula in the priority document is different from the structural formula provided in the instant claims because the formula of the priority application does not include all of the structural limitations of the instant claims. For example, the structural formula in the priority application does not include R_3 , (see pages 1-2 of the priority document).

Applicant's arguments have been fully considered but they were not deemed to be persuasive. Applicant submits that 'the claims of the present application differ from the UK priority application', however, argues that 'the subject matter not disclosed in the priority application is not present in Mueller, and the rest of the claim predates the reference under 35 USC 102(e)'.

MPEP 2136.05 provides that - The reference can be antedated by applicant's earlier foreign priority application if 35 USC 119 is met and if the foreign application "supports" (conforms to 35 U.S.C. 112, first paragraph, requirements) all the claims of the U.S. application. 35 U.S.C. 112 requires that: "The specification shall contain a **written description** of the invention, and of the manner and process of making and using it, in such full, clear,

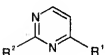
concise, and **exact terms** as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention”.

In the instant application, the claims as presented were not supported by the foreign priority application as required by 35 USC 119, and therefore, the instant claims are not eligible for the priority date. The rejection is maintained.

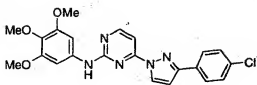
5. Claims 1-11 and 13-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Armistead et al., WO 01/60816. The reasons from the previous office action are incorporated here by reference.

Applicant's arguments have been fully considered but they were not deemed to be persuasive. Applicant argues that ‘the examiner has not shown any suggestion in the prior art for the specific molecular modifications and so the reference fails in rendering the claimed invention obvious’.

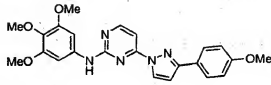
The reference, WO 01/60816 teaches a generic group of compounds of structural

formula:  and discloses several specific compounds (see Table 1), see for example, the compounds 33 and 34 (depicted below for convenience):

33



34



The reference compounds are taught to be useful as pharmaceutical agents having kinase inhibiting activity, see the abstract. The instant claims recite a genus of formula I which differs from the reference disclosed compounds by having the pyrazole ring attached through the 1-position to the pyrimidine ring as compared to the 3-position in the claims. One of ordinary skill in the art would have been motivated to prepare the instantly claimed compounds that differ from the reference compounds by the point of attachment of the pyrazole ring, with the reasonable expectation that such structurally analogous compounds would have similar properties and therefore, the same use as taught for the reference compounds, in the absence of a showing to the contrary. One of ordinary skill in the art in possession of the reference disclosed compounds, for example the compounds 33 and 34, with the disclosed pharmaceutical activity would have immediately recognized that a single change in substitution such as varying the position of attachment of the pyrazole ring to the pyrimidinyl ring can be done without the loss of the pharmacological activity. A single change in substitution of the reference disclosed compound would have resulted in a compound falling within the claimed structural formula I, having the pyrazol-3-yl substituent as compared to the pyrazol-1-yl for the reference compound.

Applicant cites *Takeda v. Alphapharm* to support the argument. However, the situation is *Takeda* is different from the instant case. The court in that case ruled that ‘one of ordinary skill in the art would not have been prompted to modify the reference compound, using the steps of homologation **and** ring-walking, to synthesize the claimed compounds’. Contrary to the cited *Takeda* ruling, in the instant application, one of ordinary skill in the art needs to modify the reference compound by changing the position of attachment on the pyrazolyl ring to arrive at the instantly claimed compounds of formula I.

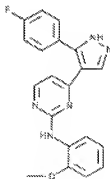
6. Claims 1-7, 10-11 and 13-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Anantanarayan et al., WO 00/31063. The reasons from the previous office action are incorporated here by reference.

Applicant's arguments have been fully considered but they were not deemed to be persuasive. Applicant argues that 'the examiner has not shown any suggestion in the prior art for the specific molecular modifications and so the reference fails in rendering the claimed invention obvious'.

The reference, WO 00/31063 teaches a generic group of compounds of structural



formula: (2A) and discloses several specific compounds, see for example, the compound of Example A-326 (depicted below for convenience):



The reference compounds are taught to be useful as pharmaceutical agents, see pages 23-25. The instant claims exclude the reference disclosed compound, however, include compounds which differ from the reference disclosed compound by, for example, a -CH₂ group. Examples of such analogs include compounds of formula I wherein R₁ is ethoxy; or R₂ is methyl; etc. One of ordinary skill in the art would have been motivated to prepare the instantly claimed compounds

that differ by a CH₂ group from the reference compounds, with the reasonable expectation that such structurally analogous compounds would have similar properties and therefore, the same use as taught for the reference compounds, in the absence of a showing to the contrary. One of ordinary skill in the art in possession of the reference disclosed compounds, for example the compound of Example A-326, with the disclosed pharmaceutical activity would have immediately recognized that a single change in substitution, such as replacing the methoxy group with ethoxy, can be done without the loss of the pharmacological activity. A single change in substitution of the reference disclosed compound would have resulted in a compound falling within the claimed structural formula I.

Applicant cites *Takeda v. Alphapharm* to support the argument. However, the situation is *Takeda* is different from the instant case. The court in that case ruled that ‘one of ordinary skill in the art would not have been prompted to modify the reference compound, using the steps of homologation **and** ring-walking, to synthesize the claimed compounds’. Contrary to the cited *Takeda* ruling, in the instant application, one of ordinary skill in the art needs to modify the reference compound A-326 by a single modification – i.e., by replacing the methoxy with an ethoxy group (for R₁); **or** substituting methyl in place of hydrogen (for R₂); etc. to arrive at the instantly claimed compounds of formula I.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deepak Rao whose telephone number is (571) 272-0672. The examiner can normally be reached on Monday-Friday from 8:00am to 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson, can be reached at (571) 272-0661. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

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system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

**/Deepak Rao/
Primary Examiner
Art Unit 1624**

December 5, 2008